

REMARKS

Claim 1 had been previously cancelled without prejudice or disclaimer in a preliminary amendment filed October 23, 2002. However, in the restriction requirement, the Examiner referred to claim 1. This amendment reiterates the cancellation of claim 1.

Applicants' representative respectfully traverses all restrictions expressed in the Office Action. Applicants' representative traverses the restriction requirement on the basis that (1) the groupings do not conform to the patent statute; (2) Office Action fails to establish a prima facie showing for the restriction; and (3) the groupings are highly unreasonable. Applicants' representative also notes the presence of linking claims that require all claims to be examined should a linking claim be allowed. These points are discussed in detail below.

Applicants hereby provide a record of Office interviews involving the application, in which Applicants' representative consulted with Examiner James Housel regarding this restriction requirement, and Examiner Housel kindly offered his assistance in resolving this matter. Applicants' representative sincerely thanks Examiner Housel for his assistance.

Clarification of restriction requirement

As a preliminary matter, Applicants' representative notes that the restriction is unclear. The use of the word "specific" in each of the 108 groups appears to mean electing a particular analog (such as a particular carbohydrate) and a particular immunogen. However, Section IV of the Office Action also requires election within a group of a specific analog such as specific carbohydrate, lipid, etc., and a specific immunogen such as the ones recited at claim 41, regardless whether the specific examples including immunogen and analog molecules are in the same class or in a different class from other examples including immunogen and analog molecules.

In addition, upon first reading it appears that each of the groups listed in Section III of Office Action is considered to be an independent and distinct invention, and no linking claim is

present. However, in the context of Section V of the Office Action, it appears that the Examiner has identified certain of the linking claims that link the various groupings that the Examiner has made.

Applicants' representative has therefore interpreted the restriction requirement of Section III of the Office Action as well as from conversations between Applicants' representative and Mr. Housel of the Patent and Trademark Office as an election requirement in which Applicants must elect one of the groups for prosecution and, upon allowance of a generic or linking claim, the Examiner will examine the other groups in this application.

Claims are linked, and the MPEP requires linked claims to be examined in the same application

Applicants' representative wishes to particularly emphasize that certain claims link all of the claims together in this application pursuant to MPEP 809 and 809.03, and these linking claims must be examined at this time per MPEP 809. Claim 22 links all pending claims, since all claims depend from claim 22. Claims 22, 48, 49, and 50 are also linked as product, process of making, and a process of using. Applicants' representative notes that the MPEP, in directing examiners on properly dealing with restriction matters, states "should any linking claim be allowed, the restriction requirement must be withdrawn..." and the withdrawn claims must be fully examined for patentability (MPEP 809, 809.04). Consequently, should any of the linking claims or the generic claims be found allowable, the MPEP requires withdrawal of the restriction requirement and full examination of the remaining linked claims for their patentability.

The restriction requirement of Section III of the Office Action does not conform to 35 U.S.C.

Sec. 121

Applicants' representative first traverses the restriction requirement of Section III of the Office Action on the basis that the groupings made by the Examiner do not conform to the patent statute.

The Examiner must focus on what the Applicants claim, not on categories that the Examiner may divide an individual claim into without regard for what the Applicants have claimed.

35 U.S.C. Sec. 121 specifies that a restriction is proper “[i]f two or more independent and distinct inventions are claimed in one application.” Courts have stated that a restriction requirement under this section cannot be applied to one claim; in other words, a single claim cannot be subdivided into separate, restricted groups. See *In re Harnish*, 631 F.2d 716, 721 (CCPA 1980) (stating that “court held that Section 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made”). “If...a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicants, it is not inconceivable that a number of the fragments would not be described in the specification.” *In re Weber*, 580 F.2d 455, 458 (CCPA 1978).

The Examiner has divided Applicants’ claims into fragments. None of the criteria for grouping claims that the Examiner applied is found in one claim. It would be necessary to amend Applicants’ claims in order to obtain the groupings that the Examiner applied.

A comparison of groups 38 and 39 illustrates how the groupings are incorrect. Group 38 consists of claims 48-49, “wherein the analog molecule of a conjugate is a specific carbohydrate, wherein the external immunogen is a specific drug, classified in Class 424, subclass 193.1.” Group 39 also consists of claims 48-49, but are to be limited such that the analog molecules are a “specific lipid,” and the external immunogen is a “specific drug.” Group 39 is also classified in Class 424, subclass 193.1. Claims 48 and 49 depend from claim 29, which in turn depends from claim 22. None of these claims contains a limitation on what the analog molecules may be or what the external immunogen may be. To restrict the claims in the manner the Examiner requires would require Applicants to amend the claims and introduce limitations to conform to the classifications into which the Examiner is classifying the claims, thereby fragmenting the claims.

This is not restriction practice as contemplated by the statute. The statute requires election among claims as written, not forced election into arbitrary classifications that an Examiner provides. The Examiner incorrectly subdivided the claimed subject matter into various

classifications not supported by the claims. The Examiner has in essence applied a nonstatutory election of species type requirement to claims where the particular limitations the Examiner uses as the basis for restriction are not present in that combination in the language of the claims.

Applicants' representative notes that other of the claims not used in the example above contain Markush groupings specifying particular analog molecules or particular immunogens. However, Applicants' claims do not recite even one of the 108 groups that the Examiner has applied to the present claims. The Markush grouping of analog molecules recites eight molecules. But none of the claims specifies particular analog molecules with particular immunogens. The Examiner has applied highly restrictive restriction requirements¹ to Applicants' claims by treating the claims as if Applicants had explicitly claimed the particular combinations of features that the Examiner uses to derive 108 groups. The Examiner can only restrict based on Applicants' claims, not based on requiring Applicants to amend all of its elected claims to conform to the Examiner's claim classifications.

The Office Action fails to establish a prima facie showing for restriction

Applicants' representative further traverses the restriction requirement on the basis that the groupings are incorrect and/or were not supported with sufficient explanation.

MPEP 803 states that "a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02." This *prima facie* showing can be rebutted. *Id.* Applicants submit that the Examiner did not make a *prima facie* showing based on the following.

The Office Action at page 25 reasons that each of groups 1-37 is unrelated to the other groups because the "products as claimed differ with respect to their structure and physiochemical

¹ Even peptides, polypeptides, and proteins have been used as the basis for separate classifications in the restriction requirement, yet each of these is within the same chemical class. See, e.g., group 6 and group 7. The fine parsing of Applicants' 31 claims into 108 groups is simply not supported by the patent statute and thus is improper.

properties.” However, claim 22, from which all other claims depend, specifies common physiochemical characteristics for compositions within the scope of claim 22. The analog molecules conjugated to a chemically defined valency platform molecule (1) bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and (2) lack T cell epitopes. There are therefore common characteristics, contrary to the Examiner’s contention.

The Office Action also indicates that a prior art search would include literature and would be a burden on the Examiner. Applicants’ representative interprets this to mean that the Examiner is asserting there would be an undue burden on the Examiner. However, Applicants’ representative notes that groups 1-73 are all within the same class and subclass (424 & 193.1), and groups 74-108 are all within a second class and subclass (435 & 69.1). It is not an undue burden to search a reasonable number of species within two classifications, and as noted above, Applicants’ claims specify only 8 analog molecules. In view of this, Applicants’ representative submits the burden involved in searching Applicants’ claimed subject matter within two Patent Office search classifications is not undue, and therefore the claims should be examined without restriction.

The restriction requirement is unreasonable

Applicants’ representative further traverses on the basis that such groupings are highly unreasonable. Such groupings, were they permitted under the statute, would unduly raise the cost of patent prosecution to prohibitive levels. According to the restriction requirement applied to the pending claims, filing fees alone for the 108 groups would total \$41,580 at a minimum (108 applications x \$385 minimum filing fee per application for a small entity), and an original application containing only 31 claims would issue as 108 separate patents. The estimated cost does not account for the further restriction applied by Section IV of the Office Action, which has the potential to raise filing costs and number of applications by an order of magnitude. In addition, the Patent and Trademark Office would be deluged should a patent applicant have a high enough budget that it would file 107 or more divisional applications. The Office’s infrastructure would likely not be capable of handling the documents or files associated with the substantial increase in filings that

the Office would encounter, even in a “paperless” Office. The impact on business would be significant if the Office sanctioned the restriction practice that was applied in this instance.

Provisional election of group 14 to comply with restriction requirement expressed in Section III of the Office Action

Applicants’ representative in providing a complete reply to Section III of the Office Action elects the claims of group 14, but with traverse as discussed above and with reservation as discussed below in the last section.

Section IV of the Office Action contains an additional restriction not supported by the patent statute

It appears from Section IV of the Office Action that a further restriction under 35 U.S.C. Sec. 121 is required for the elected group. The reasons stated in the Office Action for requiring further restriction under 35 U.S.C. Sec. 121 are the same reasons used to establish different claim groupings, that the compositions are patentably distinct because they differ with respect to their structures, physiochemical properties, and mode of action. Applicants’ representative traverses this further restriction for at least the reasons stated above. The restriction is not supported by the patent statute because the restriction fragments individual claims – none of the limitations expressed in the restriction requirement are present in any single claim. The rationale provided by the Examiner does not support restriction for the reasons discussed above for Section III of the Office Action. Further, the restriction applied by the Examiner would produce unreasonable results of high cost. Applicants’ representative could understand if the Examiner issued a nonstatutory requirement for election of a species for search purposes, in order to provide a starting point for a search; however, a restriction under 35 U.S.C. Sec. 121 is improper for the reasons above and should be withdrawn.

Provisional election to conform with Sections IV, V and VI of the Office Action

Again in order to be fully responsive, Applicants’ representative elects claims to a composition in which the peptide analog is SEQ ID No. 7, the specific immunogen is melittin, and

the analog and the immunogen are in the same chemical class, with traverse as discussed above and with reservation as noted in the last section below. Applicants believe that this election also satisfies the election requirement of Section V. Claims readable on the election include (at least) claims 22-27, 29-35, 37, 38, 42, 43, 46, 48-51.

Generic claims and linking claims warrant examination of all claims in this application

Applicants' representative also notes the Examiner's recognition in Section V of the Office Action of generic claims pending in this matter and notes that Applicants will be entitled to consideration of claims to additional species written in dependent form or otherwise including all limitations of an allowed generic claim. Applicants' representative wishes to reiterate that the linked claims present in this application require examination of all claims pursuant to MPEP 809, which states, "should any linking claim be allowed, the restriction requirement must be withdrawn..." and the withdrawn claims must be fully examined for patentability.

Provisional elections

In view of the above, Applicants' representative requests that the Examiner withdraw all restriction requirements under 35 U.S.C. Sec. 121 as applied to the claims. In the event that the Examiner disagrees with the withdrawal of all restriction requirements, Applicants' representative requests that the Examiner adhere to the recognized election of species practice that involves the election of subject matter in a Markush grouping as specified by claim 26 in this instance. In this event, Applicants' representative provisionally elects subject matter in which the analog molecule comprises a peptide, polypeptide or protein (without specifying an immunogen). Other elections have been made above in the event such elections are necessary.

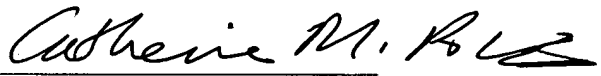
None of the elections above is to be read as acquiescence to the propriety of the particular restriction requirement to which the elections correspond. Applicants expressly reserve his/her right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

CONCLUSION

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 252312005706. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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